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Art*

PATENT
Customer No. 20,462
Attorney Docket No. P32685

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Storm, et al.

Application No.: 09/689,483

Filed: October 12, 2000

For: NOVEL METHOD OF TREATMENT

)
)
) Group Art Unit: 1615
)
) Examiner: Rachel Bennett
)
)

*OK to
infr
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RUB*

Commissioner for Patents
Washington, DC 20231

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56, Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449 Forms. This Information Disclosure Statement is being filed after the mailing date of a Final action. Nonetheless, Applicants respectfully request that the Examiner waive the rule and consider this Information Disclosure Statement because it merely seeks to bring before the Examiner references that have been previously identified or submitted in this or in the copending cases. Moreover, these are the same references cited in copending application USSN 09/971,560, which is not yet under Final. If the Examiner declines to consider these references, Applicants respectfully request that these papers be placed in the file pursuant to 37 C.F.R. § 1.97(i). Should the Examiner consider this Information Disclosure Statement, Applicants authorize the Office to deduct the fee of \$180.00 as specified by Section 1.17(p) from Deposit Account 19-2570.

To facilitate the Examiner's review of these documents, the documents are listed in separate PTO 1449 Forms according to the source from which the documents were noted. Copies of the listed documents are similarly submitted in separate groups according to each PTO 1449 Form.

Applicants also bring to the attention of the Examiner the following chart which identifies possibly related copending applications/patents, including those previously identified but summarized here again for the Examiner's convenience. Should the Examiner wish copies of any of these applications, please advise the undersigned at the number below.

US Application Number	Examiner	GSK Number
USSN 08/722,259 USSN 09/788,948	J. Goldberg D. Jagoe	P50383X2 P50383X2D1
USSN 10/321,875 (continuation of 08/993,898) WO 94/16696	(not yet assigned) J. Goldberg	P30580C4 P30580C3X2
USSN 09/544,019 USSN 10/115,700 (US 2002-0168405 A1 Nov. 14, 2002)	R. Bennett R. Bennett	P32554 P32554D1
US Pat. 6,294,199 USSN 09/911,905 (US 2002-0001616 A1 Jan. 3, 2002)	R. Bennett R. Bennett	P32555 P32555D1
USSN 09/689,483 USSN 09/971,560	R. Bennett R. Bennett	P32685 P32685 C1
USSN 09/974,596 (US 2002-0128251 A1 Sep. 12, 2002)	M. Young	P32687
USSN 09/974,572	M. Young	P32688

Applicants submit the following PTO 1449 Forms, identified as A, B, C, D, E, F, and G:

A. Documents cited in the present specification but not yet submitted to the Office.

- B. Documents from the files of U.S. Serial No. 08/993,898, entitled "Pharmaceutical Formulations Comprising Clavulanic Acid Alone or in Combination with Other Beta-Lactam Antibiotics" (Applicants' reference number P30580C3X2) and its continuation application, U.S. Serial No. 10/321,875, filed on December 12, 2002, (Applicants' reference number P30580C4), but not yet submitted in this case.
- C. Documents from the file of U.S. Serial No. 09/544,019, entitled "Novel Method of Treatment," (Applicants' reference number P32554), but not yet submitted in this case.
- D. Documents cited by the Office in the applications set forth in the chart above. These documents may have been previously submitted, but Applicants include them nonetheless for the convenience of the Examiner.
- E. Documents cited in the prior Response filed 22 November 2002 in reply to the Office Action of 22 May 2002. While some of these documents have been previously submitted, they are resubmitted here for the Examiner's convenience.
- F. Opinions, Orders, and trial transcripts for the case captioned *Geneva Pharmaceuticals, Inc. et al. v. GlaxoSmithKline PLC, et al.* (E.D. Va. 2002). The opinion (reported as 2002 WL 1802991) finds that U.S. Patent Nos. 4,525,352; 4,529,720; and 4,560,552 are invalid. The opinion also references prior decisions in the matter which found invalid U.S. Patents Nos. 6,218,380; 6,031,093; 6,048,977; and 6,051,703. This matter is now on appeal at the United States Court of Appeals for the Federal Circuit. Applicants will provide additional information regarding this matter should the Examiner so desire.
- G. Miscellaneous documents.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a complete search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 19-2570.

Respectfully submitted,

Dated: March 11, 2003

By: Jean B. Indio Reg No 32,984 for
Dara L. Dinner
Attorney for Applicant
Reg. No. 33,680

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TO

Name: Examiner Rachel Bennett
Firm: USPTO
Fax No.: 703-746-5315
Phone No.: 703-308-8779
Subject: Appln of Storm et al.
Your File No.: Appln No. 09/689,483

FROM

Name: Jean B. Fordis
Phone No.: 650-849-6607
Fax # Verified by: jbf
Pages (incl. this): 8
Date: March 24, 2003
Our File No.: P32685 (04012-0331)

Confirmation Copy to Follow: No

Examiner Bennett:

Thank you again for your kind suggestion of submitting corrected IDSs in this case. I hope this resolves the issue. If not, please do contact me at 650-849-6607.

Jean Fordis

If there is a problem with this transmission, notify fax room at (650) 849-6600 or the sender at the number above.

This facsimile is intended only for the individual to whom it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If you have received this facsimile in error, please notify the sender immediately by telephone (collect), and return the original message by first-class mail to the above address.

15/ 2nd Suppl
Prior Art

PATENT

Customer No. 20,462

Attorney Docket No. P32685

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Storm et al.

Application No.: 09/689,483

Filed: October 12, 2000

For: NOVEL METHOD OF TREATMENT

Group Art Unit: 1615

Examiner: Rachel Bennett

Commissioner for Patents
Washington, DC 20231

Sir:

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56, Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449 Forms. This Information Disclosure Statement is being filed after the mailing date of a Final action. Nonetheless, Applicants respectfully request that the Examiner waive the rule and consider this Information Disclosure Statement because it merely seeks to bring before the Examiner references that have been previously identified or submitted in this or in the copending cases. Moreover, these are the same references cited in copending application USSN 09/971,560, which is not yet under Final. If the Examiner declines to consider these references, Applicants respectfully request that these papers be placed in the file pursuant to 37 C.F.R. § 1.97(i). Should the Examiner consider this Information Disclosure Statement, Applicants authorize the Office to deduct the fee of \$180.00 as specified by Section 1.17(p) from Deposit Account 19-2570.

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FEE SCHEDULE	
ACCOUNT NO.	
DEPOSIT ACCOUNT NO.	
19	2570
1806	180.00

03/27/2003 CBETANCO 00000001 192570 09689483

01 FC:1806 180.00 CH
383940v2

Applicants resubmit the following U.S. Patents and U.S. applications for the Examiner's specific consideration of possible double patenting rejections. To facilitate the Examiner's review of these documents and avoid the wasteful reproduction of specifications, Applicants submit only the claims issued or pending in these matters, but provide the patent number or serial number in the chart below. Should the Examiner wish copies of any of these documents, please advise the undersigned at the number below.

US Patent or Application Number	Examiner	GSK Number
USSN 09/544,019 USSN 10/115,700	R. Bennett R. Bennett	P32554 P32554 D1
US Pat. 6,294,199 USSN 09/911,905	R. Bennett R. Bennett	P32555 P32555 D1
USSN 09/971,560	R. Bennett	P32685 C1
USSN 09/974,596	M. Young	P32687
USSN 09/974,572	M. Young	P32688

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form. Should the Examiner conclude that any of these claims form the basis of a double patenting rejection, the Examiner is invited to contact the undersigned to discuss the possible filing of a Terminal Disclaimer.

This submission does not represent that a complete search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are

material or constitute "prior art." Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 19-2570.

Respectfully submitted,

Dated: March 11, 2003

By: Jean B. Fiedler By No 32984 for
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